REMARKS

I. STATUS OF THE CLAIMS.

Claims 139-168 are presently pending with entry of this Amendment. Claims 1-138 were previously canceled without prejudice. Claims 139-143 have been amended and new claims 159-168 have been added. Support for the amendments and new claims is provided throughout the application. None of the amendments or new claims presents any new matter.

II. AMENDMENTS TO THE SPECIFICATION.

The specification was amended to correct an inadvertent typographical error in paragraph [0054]. The specification incorrectly stated the human EpCAM shown in SEQ ID NO:41 is 265 amino acids in length. However, as is plainly evident, the sequence shown in SEQ ID NO:41 is 314 amino acids in length. That the human EpCAM sequence is 314 amino acids in length is also confirmed by the remainder of the information presented in paragraph [0054]. No new matter has been added by this amendment.

III. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH.

A. The Claims Satisfy the Written Description Requirement.

Claims 140, 143, and 152-155 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time that application was filed, had possession of the claimed invention. Office Action, p. 2. Specifically, the Examiner finds that:

> Applicants have added new claims including in particular claims 140 and 143, which recited "...amino acid residues 24-265 of SEQ ID NO:4". Applicants assert support for this new claim language can be found in the specification, including page 32, paragraph 00112. The Examiner has reviewed the entire specification, including the designated passage and does note amino acid residues 81-265, but does not see support of Applicants' contemplation of a polypeptide comprising amino acid residues 24-265 of SEQ ID NO:4. Applicants should pointedly express where in the specification support can be found for this limitation or delete the new matter.

Id., pp. 2-3.

This rejection is respectfully traversed. Paragraph [00112] on page 32 of the specification clearly provides support for claims 140 and 143, as Applicants indicated on page 7 of the previously filed Preliminary Amendment. Exemplary passages in paragraph [00112] that support these claims are shown in bold underlining below:

> [00112] One aspect of the invention pertains to an **isolated, recombinant or non-naturally occurring polypeptide comprising a polypeptide sequence that has at least about** 80, 85, 90, 91, 92, 93, 94, 95, **96**, 97, 98, 99, **or 100% sequence identity to an amino acid subsequence of the polypeptide sequence of SEQ ID NO:4, which amino acid subsequence comprises or consists essentially of amino acid residues** 81-265 (i.e., residue 81 through and inclusive of residue 265), 82-265, 22-265, 23-265, **24-265**, or 1-265 **of SEQ ID NO:4**, wherein the resultant polypeptide has an ability to induce at least one type of immune response against hEpCAM or an antigenic fragment thereof.

Specification, p. 32, paragraph [00112].

Thus, paragraph [00112] explicitly describes a polypeptide having at least 96% identity to a sequence comprising amino acid residues 24-265 of SEQ ID NO:4, wherein polypeptide has an ability to induce at least one type of immune response against hEpCAM or an antigenic fragment thereof. Paragraph [00112] also describes a polypeptide having at least 100% identity to a sequence comprising amino acid residues 24-265 of SEQ ID NO:4 (i.e., a polypeptide comprising a sequence residues 24-265 of SEQ ID NO:4), wherein polypeptide has an ability to induce at least one type of immune response against hEpCAM or an antigenic fragment thereof.

Support for claims 140 and 143 is also provided elsewhere in the specification, including at, but not limited to, e.g., paragraphs [00200], [00202], and [00242]. The passages in paragraph [00202], for example, which provide support for these claims are shown in bold underlining below:

> [00202] Also provided are immunogenic fragments of the sequence of SEQ ID NO:4 that have an ability to induce an immune response against hEpCAM or an antigenic fragment thereof. For example, the invention provides a **polypeptide comprising a polypeptide sequence that has at least about 96,** 97, 98, 99, **or 100% sequence identity to an amino acid sequence corresponding to** amino

> acid residues 81-265, amino acid residues 82-265, **amino acid residues 24-265** or amino acid residues 1-265 **of the sequence of SEQ ID NO:4, wherein said chimeric polypeptide has an ability to induce an immune response against hEpCAM or an antigenic fragment thereof**.

Specification, p. 68, paragraph [00202].

For at least these reasons, Applicants submit that the rejection is improper and respectfully request that it be withdrawn.

Claims 139-141, 143, and 145-158 were rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to satisfy the written description requirement. Office Action, p. 3. Specifically, the Examiner finds that "[t]he written description in this case only sets forth SEQ ID NO:4 and amino acid residues 81-265 of SEQ ID NO:4 as a polypeptide and fragment of said polypeptide able to induce an immune response against human epithelial adhesion molecule (EPCAM), therefore the written description is not commensurate in scope with the claims drawn to polypeptide sequences with less than 100% sequence identity to amino acid sequences 24-265 and 81-265 of SEQ ID NO:4 and *a* polypeptide that is 96% sequence identical to SEQ ID NO:4." *Id.*, p. 3 (emphasis in original).

This rejection is respectfully traversed. The specification unmistakably supports the claimed polypeptides, including at, but not limited to, e.g., paragraphs [00112], [00200], [00202], and [00242]. Exemplary passages in paragraphs [00112] and [00202] that provide express support for the rejected claims are shown in bold underlining below:

> [00112] One aspect of the invention pertains to an **isolated, recombinant or non-naturally occurring polypeptide comprising a polypeptide sequence that has at least about** 80, 85, 90, 91, 92, 93, 94, 95, **96, 97,** 98, 99, **or 100% sequence identity to an amino acid subsequence of the polypeptide sequence of SEQ ID NO:4, which amino acid subsequence comprises or consists essentially of amino acid residues 81-265** (i.e., residue 81 through and inclusive of residue 265), 82-265, 22-265, 23-265, **24-265**, or 1-265 **of SEQ ID NO:4**, wherein the resultant polypeptide has an ability to induce at least one type of immune response against hEpCAM or an antigenic fragment thereof.

Specification, p. 32, paragraph [00112].

> [00202] Also provided are immunogenic fragments of the sequence of SEQ ID NO:4 that have an ability to induce an immune response against hEpCAM or an

> antigenic fragment thereof. For example, the invention provides a **polypeptide comprising a polypeptide sequence that has at least about 96, 97,** 98, 99, or **100% sequence identity to an amino acid sequence corresponding to amino acid residues 81-265,** amino acid residues 82-265, **amino acid residues 24-265** or amino acid residues 1-265 **of the sequence of SEQ ID NO:4, wherein said chimeric polypeptide has an ability to induce an immune response against hEpCAM or an antigenic fragment thereof.**

Specification, p. 68, paragraph [00202].

Thus, the specification expressly describes a polypeptide comprising a polypeptide sequence having at least 96% (or 97%) sequence identity to a polypeptide sequence comprising amino acid residues 81-265 of SEQ ID NO:4, wherein the polypeptide has an ability to induce an immune response against hEpCAM or an antigenic fragment thereof. The specification also explicitly describes a polypeptide sequence having at least 96% (or 97%) sequence identity to a polypeptide sequence comprising amino acid residues 24-265 of SEQ ID NO:4, wherein the polypeptide has an ability to induce an immune response against hEpCAM or an antigenic fragment thereof. Additionally, the specification describes a polypeptide comprising a polypeptide sequence having at least 96% sequence identity to SEQ ID NO:4, wherein the polypeptide has an ability to induce an immune response against hEpCAM or a fragment thereof.

The Examiner's argument that the written description requirement is not met because "the skilled artisan cannot envision the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred" (Office Action, p. 4) is unfounded. Each of independent claims 139, 140 and 142 specifies a polypeptide having a particularly defined structure (e.g., at least 97% identity to residues 24-265 of SEQ ID NO:4) and functional activity (e.g., an ability to induce an immune response against human EpCAM or an antigenic variant thereof). The specification discloses sufficiently detailed descriptions of the structures of such claimed polypeptides and a variety of assays for determining whether a particular polypeptide is able to induce an immune response against human EpCAM or an antigenic fragment thereof. See, e.g., the assays disclosed in Examples 2, 4, 5, 6, 7, and 8 (e.g., pages 199-212).

The Examiner's contention that "support for a polypeptide and variants and complements defined as 96% sequence identical to the unsupported amino [sic] residues 24-265 seems to be

nonexistent" and "insufficient to support the generic claims as provided by the Interim Written Description Guidelines" (Office Action, pp. 4-5) similarly lacks merit. Applicants submit that all of the presently pending claims meet the written description requirement as elucidated by the Federal Circuit and the USPTO's Written Description Guidelines. Applicants' disclosure clearly provides sufficiently detailed and relevant identifying characteristics of each claimed genus. Applicants provide specific chemical structural features common to members of each genus that distinguish them from others, disclose that each such member has the specified function, disclose a specific correlation between the claimed structures and the asserted function, and provide a specific description of the assays one can use to test whether a particular structural sequence has the asserted function. For example, Applicants provide explicit description of particular immunogenic polypeptides possessing the claimed structures (see, e.g., paragraphs [00108], [00111], [00112], [00202]) and also provide detailed guidance as to particular amino acid substitutions that can be made in such polypeptide sequences while retaining the ability to induce an immune response (see, e.g., paragraphs [00113], [00143]-[00184], [00194], [00195], [00198], [00200], [00201]). The disclosed function is sufficiently correlated to a particular structure, since the functional activity of the claimed polypeptides, including those defined by claims 139-141, can be readily determined by the assays provided in the specification.

Moreover, the law is clear that all possible variants of a claimed genus need not be described to satisfy the written description requirement. Rather, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Here, the specification discloses relevant identifying characteristics and a sufficient number of representative species of the genus defined by each of claims 139, 140, and 141.

Based on Applicants' detailed disclosure, one of ordinary skill in the art would have recognized that Applicants were in possession of the claimed polypeptides and compositions thereof at the time of filing.

For at least these reasons, Applicants respectfully submit that the rejection is improper and request that it be withdrawn.

B. The Claims Are Sufficiently Enabled.

Claims 139-141, 143, and 145-158 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably provide enablement commensurate with the scope of the claimed invention. Office Action, p. 5. In particular, the Examiner contends:

> Claims 139-141 and 143-158 are broadly drawn to an isolated polypeptide comprising a sequence which is at least 96% identical to amino acid residues 81-26 [sic] and 24-265 sequence [sic] SEQ ID NO:4 and a polypeptide sequence, which has at least 96% sequence identity [sic] 81-265 and 24-265 of SEQ ID NO:4. The specification while being enabling for the polypeptide identified as SEQ ID NO:4 and a peptide comprising 81-265 amino acid residues, does not reasonably provide enablement for variants that have at least 96% sequence identity and fragments of the polypeptide that more than likely do not encode protein with the ability to induce an immune response against human EpCAM. Moreover, a polypeptide sequence probably does not encode a protein. There is no guidance as to how to make these divergent sequences. The polypeptides with 96% sequence identity to SEQ ID NO:4 and to fragments of SEQ ID NO:4 may possess function that is not commensurate with the functions of the native protein. These proteins may not maintain the activities proposed in the specification. Likewise, it would seem that specific function(s) would be required to make the encoded protein useful for the applications disclosed in the specification...The specification provides essentially no guidance as to which of the infinite possible choices is likely to be successful...
>
> From the discussion above, it is clear that the predictability of changes to the nucleic acid sequence and its forthcoming amino acid sequence is practically nil as far as biological activities are concerned. The specification fails to provide sufficient guidance to enable one of ordinary skill in the art to make and use the claimed nucleic acids in a manner reasonably correlated with the broad scope of the claims. Without such guidance, the changes which must be made in the mutant polypeptides of SEQ ID NO:4, which results in proteins with 96% identify comprising 24-265 and 81-265 of SQ ID NO:4 is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue.

Office Action, pp. 6-7 (emphasis in original).

This rejection is respectfully traversed as follows.

Courts have outlined several factors that may be considered in determining whether a specification does not satisfy the enablement requirement. These include: (1) the breath of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *See, e.g., In re Wands*, 858 F.2d 731, 737; 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

A review of these factors as applied to claims 139, 140, and 141, and the claims dependent thereon, confirms that these claims are fully enabled. As explained in the specification, wild-type full-length human EpCAM is a membrane-bound protein comprising 314 residues (SEQ ID NO:41). See paragraph [0054]. Amino acid residues 1-265 of SEQ ID NO:41 correspond to the signal peptide (residues 1-23), propeptide (residues 24-80), and extracellular domain (residues 81-265). *Id.* The signal peptide of human EpCAM is proteolytically cleaved from the full-length polypeptide upon processing and expression. *Id.* Known immunogenic subsequences of full-length human EpCAM include, but are not limited to, e.g., the sequence comprising the propeptide and extracellular domain (residues 24-265) and the extracellular domain sequence (residues 81-265). See paragraph [0056]. As explained in the specification, Applicants' claimed EpCAM variants include similar domains.

Independent claim 139 specifies an isolated or recombinant polypeptide comprising a polypeptide sequence that has at least 97% sequence identity to a polypeptide sequence comprising amino acid residues 81-265 of SEQ ID NO:4, wherein the isolated or recombinant polypeptide has an ability to induce an immune response against human EpCAM or an antigenic fragment thereof. The sequence comprising residues 81-265 of SEQ ID NO:4 corresponds to the extracellular domain of SEQ ID NO:4. See, e.g., paragraph [00198].

Independent claim 140 specifies an isolated or recombinant polypeptide comprising a polypeptide sequence that has at least 97% sequence identity to a polypeptide sequence comprising amino acid residues 24-265 of SEQ ID NO:4, wherein the polypeptide has an ability to induce an immune response against human EpCAM or an antigenic fragment thereof. The sequence comprising residues 24-265 of SEQ ID NO:4 corresponds to the propeptide and extracellular domain of SEQ ID NO:4. See, e.g., paragraph [00200].

Independent claim 141 specifies an isolated or recombinant polypeptide comprising a polypeptide sequence that has at least 96% sequence identity to the polypeptide sequence of SEQ ID NO:4, wherein the polypeptide has an ability to induce an immune response against human EpCAM or an antigenic fragment thereof. The sequence of SEQ ID NO:4 comprises 265 amino acid residues, which includes a signal peptide, propeptide, and extracellular domain. See, e.g., paragraph [00197].

Thus, each of the independent claims – claims 139, 140 and 141 – is specifically restricted to a polypeptide having at least 97% sequence identity to SEQ ID NO:4 or to a specific subsequence of SEQ ID NO:4 (such as residues 81-265 or residues 24-265) **and** an ability to induce an immune response against human EpCAM or an antigenic fragment thereof. Contrary to the Examiner's assertions, the breadth of each of claims 139-141 is limited.

The Examiner's contention that the specification "does not reasonably provide for variants that have at least 96% sequence identity and fragments of the polypeptide that more than likely do not encode protein with the ability to induce an immune response against human EpCAM" is entirely without merit. As discussed in detail above, the specification clearly describes: (1) polypeptides having at least 96% sequence identity to SEQ ID NO:4; (2) polypeptides having at least 96% identity to a polypeptide sequence comprising residues 81-265 of SEQ ID NO:4; and (3) polypeptides having at least 96% identity to a polypeptide sequence comprising residues 24-265 of SEQ NO:4. The specification further explicitly provides that all such polypeptides have an ability to induce an immune response against human EpCAM or an antigenic fragment thereof. See, e.g., paragraphs [00112] and [00202]. Methods for determining whether a particular polypeptide has the ability to induce such an immune response are described in detail in the specification. See, e.g., the assays disclosed in Examples 2, 4, 5, 6, 7, and 8.

The Examiner's assertion that polypeptides with "96% sequence identity to SEQ ID NO:4 and to fragments of SEQ ID NO:4 may possess function that is not commensurate with the functions of the native protein" is similarly misplaced. The polypeptides defined by claims 139-141 must have the ability to induce an immune response against human EpCAM or an antigenic fragment thereof. And, methods for determining whether a polypeptide has such function are disclosed throughout the specification. See, e.g., Examples 2, 4, 5, 6, 7, and 8.

Contrary to the Examiner's allegations, the specification provides detailed guidance regarding the structural and functional requirements of the polypeptides defined by each of claims 139-141. Applicants provide an explicit description of particular immunogenic polypeptides possessing the recited structures and also provide detailed guidance as to particular amino acid substitutions that can be made in such polypeptide sequences while retaining the ability to induce an immune response. See, e.g., paragraphs [00198], [00200], and [00201]. In addition, Applicants expressly indicate that the described polypeptides can be modified by conservative amino acid substitutions and provide explicit guidance as to the type of substitutions and how to make sequence having such substitutions. See, e.g., paragraphs [00143]-[00154].

Explicit guidance for making additional polypeptide variants of SEQ ID NO:4 and antigenic fragments thereof, such as a sequence comprising residues 81-265 or 24-265 of SEQ ID NO:4 is provided. For example, the specification describes variants of such polypeptides that include one or more specific epitope sequences, such as those epitope sequences set forth in SEQ ID NOS:47-64 and 71-76. See, e.g., paragraphs [00155]-[00163], [00194] and [00195].[1] Additional variants of SEQ ID NO:4 and additional variants of specific fragments of SEQ ID NO:4, such as variants of a sequence comprising residues 81-265 of SEQ ID NO:4 (extracellular domain) and variants of a sequence comprising residues 24-265 of SEQ ID NO:4 (propeptide/extracellular domain), are also described in detail. See, e.g., paragraphs [00164]-[00184]. Methods for ascertaining whether any such variant induces an immune response against human EpCAM or an antigenic fragment thereof are also described. See, e.g., Examples 2, 4, 5, 6, 7, and 8.

The Examiner's argument that polypeptides with 96% sequence identity to SEQ D NO:4 and to fragments of SEQ ID NO:4 "may not maintain the activities proposed in the specification" is misplaced, since each claim requires that the specified polypeptide have an ability to induce an immune response against human EpCAM or an antigenic fragment thereto.

[1] Note that the polypeptide sequence of SEQ ID NO:5 (propeptide and extracellular domain) is identical to the polypeptide sequence defined by residues 24-265 of SEQ ID NO:4. The polypeptide sequence of SEQ ID NO:1 (extracellular domain) is identical to the sequence defined by residues 81-265 of SEQ ID NO:4.

This argument is also irrelevant to whether the specification sufficiently enables one of skill to practice the claimed invention. As discussed above, the specification clearly defines how to make polypeptides having the specific structures defined by the claims (including claims 139-141) and how to test whether such polypeptides have the recited function (e.g., ability to induce an immune response against hEpCAM or antigenic fragment thereof). Based on the detailed teachings of the specification, one of ordinary skill could make a polypeptide having a structure delineated by claim 139, 140, or 141 and readily determine whether such polypeptide had an ability to induce an immune response against human EpCAM or an antigenic fragment thereof.

Additionally, the level of one of ordinary skill in the art was high in the art at the time the application was filed. Given the nature of the invention and the state of the prior art in the field at the time of filing, and the considerable direction and guidance in the specification as outlined above, one of ordinary skill in the art would certainly have been readily able to make and use the polypeptides defined by claims 139-141 and the claims dependent thereon.

Furthermore, even if some experimentation would have been necessary to make and use the polypeptides defined by claims 139-141, such experimentation would clearly not support an enablement rejection of any of these claims, or any claim dependent thereon. *Wands*, 858 F.2d at 737, 8 USPQ2d at 1404; *Atlas Powder Co. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984). It has long been established that enablement is not precluded even if some experimentation is required, provided that the amount of experimentation is not "unduly extensive." *Atlas Powder*, 750 F.2d at 1576. See also *Wands*, 858 F.2d at 737; 8 USPQ2d at 1404. Moreover, the fact that experimentation may be complex does not necessarily make it undue if the art typically engages in such experimentation. *Id.*

In this instance, based upon the detailed teachings of the specification (including the abundant guidance provided in the specification regarding specific polypeptide variants in each genus possessing the asserted functional activity and methods for making polypeptide variants having the specified structures and functional activity), the particularly defined nature of the invention, the numerous working examples, the state of the art, and the high level of skill in the art at the time the application was filed, one of ordinary skill in the art would have been reasonably able to make and use the polypeptides set forth in claim 139, 140, or 141, or any claim dependent thereon, without unduly extensive experimentation.

For at least these reasons, Applicants submit the rejection is improper. Withdrawal of the rejection is respectfully requested.

IV. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH.

The Examiner appears to reject claims 140 and 143 under 35 U.S.C. § 112, second paragraph, because the recitation "...comprising amino acid residues 24-265 of SEQ ID NO:4" in these claims allegedly does not further limit the scope of independent claim 139. Office Action, pp. 7-8.

This rejection has been overcome by the specific amendments to claims 140 and 141 discussed above. Neither amended claim 140 nor amended claim 143 depends from claim 139. With these amendments, Applicants submit that the rejection has been overcome. Withdrawal of the rejection is respectfully requested.

V. REJECTION UNDER 35 U.S.C. § 102(E).

Claims 139-158 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Publication No. 2005/0009097 A1 (effective filing date March 31, 2003) [hereinafter the '097 application]. *Id.*, p. 8. The Examiner finds that "sequence 54" disclosed in the '097 application shares at least 96% sequence identity with Applicants' polypeptide sequences comprising amino acid residues 24-265 and 81-265 of SEQ ID NO:4, respectively. *Id.* The Examiner contends that the disclosed polypeptide inherently possesses all the functions and activities of the polypeptides set forth in Applicants' claims. *Id.* This rejection is traversed in part and overcome in part.

SEQ ID NO:54 set forth in the '097 application is a 265-amino acid sequence representing a soluble form of human EpCAM comprising the signal peptide, propeptide and extracellular domain of human EpCAM. SEQ ID NO:4 of the instant application is a 265-amino acid sequence that similarly comprises a signal peptide, propeptide, and extracellular domain. In one aspect of the invention, the extracellular domain corresponds to amino acid residues 81-265 of SEQ ID NO:4, the signal peptide corresponds to amino acid residues 1-23 of SEQ ID NO:4, and the propeptide corresponds to amino acid residues 24-80 of SEQ ID NO:4. See, e.g., paragraphs [00118], [00119], and [00198].

A polypeptide sequence comprising amino acid residues 81-265 of SEQ ID NO:4 (185 residues in length) differs from a polypeptide sequence comprising residues 81-265 of human EpCAM (185 residues in length) by at least 9 amino acid residues. Thus, for example, a polypeptide sequence comprising residues 81-265 of SEQ ID NO:4 shares at least 95.1% sequence identity with a polypeptide sequence of residues 81-265 of human EpCAM (176 residues/185 total residues = 95.1%). Contrary to the Examiner's assertion, the human EpCAM sequence disclosed in the '097 application (sequence 54) does not share at least 96% sequence identity with a polypeptide sequence represented by residues 81-265 of SEQ ID NO:4. Nevertheless, in an effort to expedite prosecution, claim 139 has been amended to specify an isolated or recombinant polypeptide comprising a polypeptide sequence that has at least 97% sequence identity to a polypeptide sequence comprising residues 81-265 of SEQ ID NO:4, wherein the polypeptide has an ability to induce an immune response against human EpCAM or an antigenic fragment thereof. Although the '097 application discloses the polypeptide sequence of human EpCAM, it does not teach or suggest a polypeptide particularly defined by amended claim 139. Accordingly, Applicants submit that the rejection of claim 139 and any claims dependent thereon has been overcome.

A polypeptide sequence comprising residues 24-265 of SEQ ID NO:4 (242 residues) differs from a polypeptide sequence comprising residues 24-265 of human EpCAM (242 residues) by at least 10 amino acid residues. Thus, for example, a polypeptide sequence comprising residues 24-265 of SEQ ID NO:4 shares at least 95.8% sequence identity with a polypeptide sequence comprising residues 81-265 of human EpCAM (232 residues/242 residues = 95.8%). Contrary to the Examiner's finding, the human EpCAM sequence disclosed in the '097 application does not share at least 96% sequence identity with a polypeptide sequence represented by residues 24-265 of SEQ ID NO:4. Nevertheless, to advance prosecution, claim 140 has been amended to specify an isolated or recombinant polypeptide comprising a polypeptide sequence that has at least 97% sequence identity to a polypeptide sequence comprising residues 24-265 of SEQ ID NO:4, wherein said polypeptide has an ability to induce an immune response against human EpCAM or an antigenic fragment thereof. The '097 application does not teach or suggest a polypeptide defined by amended claim 140. Accordingly,

Applicants submit that the rejection of claim 140 and any claims dependent thereon has been overcome.

A polypeptide sequence comprising amino acid residues 1-265 of SEQ ID NO:4 differs from a polypeptide sequence comprising residues 1-265 of human EpCAM by at least 12 amino acid residues. Thus, for example, a polypeptide sequence comprising residues 1-265 of SEQ ID NO:4 shares at least 95.4% sequence identity with a polypeptide sequence of residues 1-265 of human EpCAM (253 residues/265 residues = 95.4%). Contrary to the Examiner's finding, the human EpCAM sequence disclosed in the '097 application does not share at least 96% sequence identity with a polypeptide sequence represented by residues 1-265 of SEQ ID NO:4. For clarity, claim 141 has been rewritten as an independent claim specifying an isolated or recombinant polypeptide comprising a sequence that has at least 96% sequence identity to the polypeptide sequence of SEQ ID NO:4, wherein said polypeptide has an ability to induce an immune response against human EpCAM or an antigenic fragment thereof. The '097 application does not teach or suggest the polypeptide defined by amended claim 141. Accordingly, Applicants submit that the rejection of claim 141 and any claims dependent thereon has been overcome.

For at least these reasons, withdrawal of the rejection of claims 139-158 as being anticipated by the '097 application is respectfully requested.

Claims 139-158 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,645,498 B1 (filed March 30, 1995) [hereinafter the '498 patent]. *Id.* at p. 9. The Examiner asserts that "Sequence 2, GA7366-2E" disclosed in the '498 patent shares at least 96% sequence identity with the polypeptide sequences comprising amino acid residues 24-265 and 81-265 of SEQ ID NO:4, respectively. *Id.* Applicants note that Sequence 2 in the '498 patent corresponds to a molecule designated as GA733-2E – not "GA7366-2E." Applicants assume that the Examiner intended to base the rejection on the GA733-2E molecule described in the '498 patent. This rejection is traversed in part and overcome in part as follows.

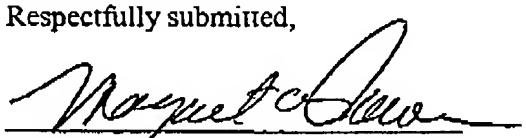
SEQ ID NO:2 of the '498 patent is a 265-amino acid sequence corresponding to a soluble form of human EpCAM comprising the signal peptide, propeptide, and extracellular domain of human EpCAM. This sequence appears the same as that disclosed in the '097 application. Applicants traverse the rejection for the same reasons as discussed above with regard to the '097

application. Applicants respectfully submit that the rejection of claims 139-158 has nevertheless been overcome by the amendments to claims 139, 140, and 141 for at least the reasons discussed above with regard to the '097 application. For at least these reasons, withdrawal of the rejection of claims 139-158 as being anticipated by the '498 patent is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application in any way, the Examiner is invited to telephone the undersigned at (650) 298-5809.

Respectfully submitted,

By: 

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